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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,237	03/10/2000	Michael M. Becker	GP068-03.CN1	5771
21365	7590	01/06/2004	EXAMINER	
GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE SAN DIEGO, CA 92121			LACOURCIERE, KAREN A	
		ART UNIT	PAPER NUMBER	
		1635		

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/523,237	BECKER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 August 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 492 and 494-555 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 505-554 is/are allowed.
- 6) Claim(s) 492,503,504 and 555 is/are rejected.
- 7) Claim(s) 494-504 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Information Disclosure Statement***

Applicant's IDS's filed June 24, 2003 and September 3, 2003 have been considered and an initialed copy of PTO form 1449 is attached to this Official action.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 492, 503 and 504 are maintained as rejected and new claim 555 is rejected under 35 U.S.C. 102(b) as being anticipated by Palfi et al. (PNAS, Vol 88, October 1991, pages 9097-9101).

Palfi et al. disclose a procedure wherein snRNPs are affinity purified using biotinylated 2'-O-methylated oligonucleotides and the purification products are subsequently identified using a primer extension assay, which requires a polymerase. In the assays disclosed by Palfi et al., the 2'-O-methylated oligonucleotides are not extended, however, they are capable of being extended. The oligonucleotides disclosed by Palfi et al. are fully modified by 2'-O-methyl and, therefore, comprise a cluster of at least 4 modified residues. Palfi et al. do not call their reagents a "kit", however, they disclose all of the reagents of the claimed kit together. Calling a set of

reagents a kit does not materially change these reagents and the inclusion of directions does not materially change a kit and, therefore, does not confer patentability on a set of reagents disclosed in the prior art. Palfi et al. anticipates claims 492, 493, 503 and 504.

### ***Response to Arguments***

Applicant's arguments filed 09-03-2003 have been fully considered but they are not persuasive. In response to the rejection of record of claims 492, 493, 503 and 504 under 35 USC 102(b) as anticipated by Palfi et al. Applicant argues that the Examiner has not demonstrated that the primers disclosed by Palfi et al. are in fact capable of being extended or that such would be inherent based on the disclosure of Palfi et al. Applicant further argues that Palfi et al. disclose a primer extension reaction, rather than a transcription based amplification reaction and, therefore, does not anticipate the claimed kits. These arguments have not been found persuasive because the primers of Palfi et al. are used in an extension reaction and are extended (as demonstrated by figure 2 of Palfi et al.). Further, the intended use of the claimed kit does not impart patentability to the claimed kit; therefore, the use of the claimed kit in a transcription based amplification reaction does not distinguish the claimed kit from the composition disclosed by Palfi et al.

Applicant argues Palfi et al. do not anticipate new claim 555 because the kit of claim 555 requires that the primer being extended include a promoter sequence. This argument is not persuasive because claim 555 does not recite a promoter. Applicant is arguing a limitation that is not found in the claim.

***Claim Objections***

Claims 494-504 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Claims 505-554 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1635

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere  
December 29, 2003

*Karen Lacourciere*  
KAREN A. LACOURCIERE, PH.D  
PRIMARY EXAMINER